Amendments the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-49. (canceled)

50. (currently amended) A pharmaceutical composition comprising substantially purified filamentous haemagglutinin (FHA) or derivative or mutant or fragment or variant or peptide thereof that is substantially endotoxin-free.

51. (currently amended) ~~A~~ The pharmaceutical composition ~~comprising FHA or derivative or mutant or fragment or variant or peptide thereof~~ of claim 50, wherein said pharmaceutical composition is effective as an adjuvant for immunization with a self or foreign antigen.

52. (currently amended) ~~A~~ The pharmaceutical composition of claim 50, further comprising ~~FHA or derivative or mutant or fragment or variant or peptide thereof in combination with~~ an antigen, ~~where~~ wherein said antigen is selected from a self-antigen and a foreign antigen.

53. (currently amended) ~~A product as claimed in any~~ The pharmaceutical composition of ~~claims~~ claim 50 ~~to 52~~ wherein said FHA comprises a product of cells activated by an FHA derivative or mutant or fragment or variant or peptide thereof ~~or a product of cells activated by these materials~~.

54. (currently amended) ~~A~~ The pharmaceutical composition ~~as claimed in~~ of claim 51 ~~to 53~~ wherein the self antigen is selected from any one or more of glutamic acid decarboxylase 65 (GAD 65), native DNA, a myelin ~~basic~~ protein, myelin proteolipid protein, acetylcholine receptor components, thyroglobulin, thyroid stimulating hormone (TSH) receptor, Japanese cedar pollen antigens, ragweed pollen antigens, rye grass pollen antigens, and dust mite antigens and feline antigens for animal, histocompatibility antigens, antigens involved in graft rejection, ~~and~~ an altered peptide ligand, beta amyloid protein, amyloid precursor protein and collagen and peptides thereof.

55. (currently amended) ~~A~~ The pharmaceutical composition ~~as claimed in~~ of claim 54 wherein the antigens involved in graft rejection include antigenic components of the graft to be transplanted into the heart, lung, liver, pancreas, kidney for graft recipients and neural graft components.

56. (canceled)

57. (currently amended) ~~A~~ The pharmaceutical composition as claimed in claim ~~56~~ 54 wherein the myelin protein is selected from the group consisting of myelin basic protein, myelin oligodendrocyte glycoprotein synthetic peptide, a MOG peptide (35-55), ~~or~~ and peptides thereof.

58-59. (canceled)

60. (currently amended) ~~A~~ The pharmaceutical composition of claim 50, further comprising ~~FHA or derivative or mutant or fragment or variant or peptide thereof in combination with~~ a TLR ligand.

61. (currently amended) ~~A~~ The pharmaceutical composition ~~as claimed in~~ of claim 60 wherein the TLR ligand is a pharmaceutically acceptable TLR ligand.

62. (currently amended) An immunomodulator comprising substantially purified FHA or derivative or mutant or fragment or variant or peptide thereof that is substantially endotoxin-free.

63. (original) A recombinant FHA having immunomodulatory effects.

64. (currently amended) A vaccine comprising substantially purified FHA or derivative or mutant or fragment or variant or peptide thereof that is substantially endotoxin-free.

65. (currently amended) ~~A~~ The vaccine ~~as claimed in~~ of claim 64 further comprising ~~FHA or derivative or mutant or fragment or variant or peptide thereof and~~ an antigen.

66. (currently amended) ~~A~~ The vaccine ~~as claimed in~~ of claim 65 wherein the FHA and antigen are present in a ~~by weight~~ ratio range of about 0.0:1 to about 100:1 by weight.

67. (currently amended) ~~A~~ The vaccine ~~as claimed in~~ of claim 65 wherein the FHA and antigen are present in a molar ratio of about 1:10 to about 10:1.

68. (currently amended) Antibodies to substantially purified FHA or derivative or mutant or fragment or variant or peptide thereof.

69. (original) A method for preparing a substantially pure preparation of FHA comprising the steps of:

dialysing a preparation of FHA to denature the protein and expose contaminating endotoxin, and

removing residual contaminating endotoxin.

70. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 69 wherein the contaminating endotoxin is lipopolysaccharide (LPS).

71. (currently amended) ~~A~~ The method ~~as claimed in~~ of 69 ~~or 70~~ wherein the endotoxin is removed using a detergent.

72. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 69 ~~to 71~~ comprising the steps of~~;~~:

priming a purification column;

adding the dialysed FHA preparation;

washing with detergent; and

eluting a substantially purified protein.

73. (currently amended) A method for the prophylaxis and/or treatment of an immune-mediated disorder comprising the step of administering an agent comprising filamentous haemagglutinin (FHA) or a derivative or mutant or fragment or variant or peptide thereof that is substantially endotoxin-free.

74. (currently amended) ~~A~~ The method ~~for the prophylaxis and/or treatment~~ of claim 73, wherein said immune-mediated disorder is an autoimmune disease ~~comprising the step of administering an agent comprising filamentous haemagglutinin (FHA) or derivative or mutant or fragment or variant or peptide thereof~~.

75. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 73 ~~or 74~~ wherein the filamentous haemagglutinin (FHA) is derived from *Bordetella pertussis* or *Bordetella bronchisepetica* or *Bordetella parapertussis* or related molecules from other bacteria.

76. (currently amended) ~~A~~ The method ~~as claimed in claims~~ of claim 73 ~~to 75~~ wherein the agent comprises a product of cells activated by FHA or derivative or mutant or fragment or variant or peptide thereof ~~or a product of cells activated by these materials~~.

77. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 76~~ wherein the agent comprises FHA in combination with self or foreign antigens or peptides thereof.

78. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 77~~ wherein the agent has an activity selected from the group of activities consisting of: promotes the generation of Tr cells in response to a self antigen; acts as an immunomodulator in vivo to promote the induction of Tr cells to coadministered self or foreign antigens; modulates pro-inflammatory cytokine production; promotes the induction of anti-inflammatory cytokines; promotes IL-10 and TGF- β production by macrophages and dendritic cells; promotes IL-6 production by macrophages and dendritic cells; synergises with LPS to promote 1L-10, TGFβ and IL-6 production by macrophages and dendritic cells; induces expression of TGFβ mRNA; inhibits inflammatory cytokines, chemokines or other inflammatory mediators; promotes dendritic cell maturation into a semi-mature phenotype; promotes dendritic cell maturation following co-activation with TLR-ligands; inhibits TLR ligand-induced dendritic cell activation; and modulates inflammatory cytokine production induced by infection or trauma.

79. (canceled)

80. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims 76 to 79~~ claim 77 wherein the self antigen is selected from any one or more of glutamic acid decarboxylase 65 (GAD 65), native DNA, myelin basic protein, myelin proteolipid protein, acetylcholine receptor components, thyroglobulin, thyroid stimulating hormone (TSH) receptor, Japanese cedar pollen antigens, ragweed pollen antigens, rye grass pollen antigens, and dust mite antigens and feline antigens for animal, histocompatibility antigens, antigens involved in graft rejection and an altered peptide ligand.

81. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 80 wherein the antigens involved in graft rejection comprise antigenic components of the graft to be transplanted into the heart, lung, liver, pancreas, kidney of graft recipients and neural graft components.

82. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims 76 to 81~~ claim 77 wherein the self antigen is selected from any one or more of a myelin protein, beta amyloid protein, amyloid precursor protein and collagen and peptides thereof.

83. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 82 wherein the myelin protein is selected from the group consisting of myelin basic protein, myelin oligodendrocyte glycoprotein (MOG) synthetic peptide, a MOG peptide (35-55), and ~~or~~ peptides thereof.

84-87. (canceled)

88. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 87~~ wherein the immunomodulatory effects of FHA on cells of the innate immune system ~~is~~ are enhanced by co-activation with a Toll-like receptor ligand.

89. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 88 wherein the Toll-like receptor ligand is ~~LPS or another toll-like receptor ligand,~~ selected from ~~any one or more~~ the group of toll-like receptor ligands consisting of LPS, CpG motifs, dsRNA, Poly (I:C) and Pam3Cys.

90-94. (canceled)

95. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim ~~94~~ 78 wherein the inflammatory cytokine is selected from any one or more of TNF-α, IFN-γ, IL-2, IL-12, IL-1, IL-23 and IL-27.

96. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim ~~94~~ 78 wherein the inflammatory chemokine is macrophage inflammatory protein-lα or macrophage inflammatory protein l β.

97-100. (canceled)

101. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 100~~ wherein FHA is in the form of an immmunomodulator, adjuvant, immunotherapeutic or anti-inflammatory agent.

102. (canceled)

103. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 102~~ wherein the immune-mediated disorder is selected from the group consisting of sepsis, ~~or~~ acute inflammation induced by infection, acute inflammation induced by trauma, ~~or~~ acute inflammation induced by injury, multiple sclerosis, Crohn's disease, inflammatory bowel disease, type 1 diabetes, rheumatoid arthritis, psoriasis, colitis, asthma, and atopic disease.

104-107. (canceled)

108. (currently amended) ~~A~~ The method ~~as claimed in any~~ of ~~claims~~ claim 73 ~~to 107~~ ~~in~~ wherein the agent is in a form for oral, intranasal, intravenous, intradermal, subcutaneous or intramuscular administration.

109. (currently amended) ~~A~~ The method ~~as claimed in~~ of claim 108 comprising repeated administration of the agent.

110. (new) The method claim 73 wherein the immune-mediated disorder is selected from the group consisting of diabetes mellitus, arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis, psoriatic arthritis, myasthenia gravis, systemic lupus erythematosis, autoimmune thyroiditis, dermatitis, atopic dermatitis, eczematous dermatitis, Sjogren's Syndrome, keratoconjunctivitis sicca secondary to Sjogren's Syndrome, alopecia areata, allergic responses due to arthropod bite reactions, aphthous ulcer, iritis, conjunctivitis, keratoconjunctivitis, ulcerative colitis, asthma, allergic asthma, cutaneous lupus erythematosus, scieroderma, vaginitis, proctitis, drug eruptions, leprosy reversal reactions, erythema nodosum leprosum, autoimmune uveitis, allergic encephalomyelitis, acute necrotizing hemorrhagic encephalopathy, idiopathic bilateral progressive sensorineural hearing loss, aplastic anemia, pure red cell anemia, idiopathic thrombocytopenia, polychondritis, Wegener's granulomatosis, chronic active hepatitis, Stevens-Johnson syndrome, idiopathic sprue, lichen planus, Graves ophthalmopathy, sarcoidosis, primary biliary cirrhosis, uveitis posterior, interstitial lung fibrosis, Alzheimer's disease and coeliac disease.